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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,953	03/17/2004	Bozidar Ferek-petric	P-9468.00	4208

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,953	FEREK-PETRIC, BOZIDAR	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 1, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on February 1, 2006. Claims 9 and 18-20 have been cancelled. No new claims have been added. Claims 1-8 and 11-17 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-8 and 10-17 are rejected under 35 U.S.C. 103(a) as being obvious over Chinchoy (U.S. 6,885,889) in view of Ferek-Petric (U.S. 5,271,392).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the

reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

4. As to Claims 1 and 4-7, Chinchoy discloses a system for chronically, read as continuously monitoring cardiac contractility, read as sensing mechanical activity of a heart and adjusting a cardiac resynchronization pacing therapy based on the sensed mechanical activity (see Chinchoy Figs. 1A, 2 and 4, Abstract, column 4, lines 63-67, column 5, lines 1-11, column 10, lines 61-67 and column 11, lines 1-5). The system of Chinchoy comprises a microprocessor-based implantable, multi-chamber cardiac pacemaker, read as a processor-based electronic cardiac pacing engine 14 (see Chinchoy column 5, lines 12-26 and column 7, lines 33-39) and a single mechanical sensor 62, located on lead 52 and adapted to detect cardiac contractions (see Chinchoy Fig. 1A, Abstract and column 6, lines 9-12). Chinchoy expressly discloses that sensor 62 is adapted to detect contractions of the left ventricular chamber. The Examiner takes the position that the mechanical sensor 62 is adapted to simultaneously detect cardiac contractions of at least a left atrial chamber, a left ventricular chamber and a right ventricular chamber based on Applicant's disclosure page 6, paragraph 17, page 18, paragraph 49 and Applicant's Fig. 7 where it is evident that the location of the sensor 62 of Chinchoy is synonymous with Applicant's and it is from this "strategically deployed" sensor that all mentioned contractions may be sensed by a single mechanical sensor. Chinchoy further disclose that the mechanical sensor 62 provides an output signal corresponding to the detected cardiac contractions to the processor based electronic pacing engine 14 to controllably produce synchronous contractions of the left ventricular chamber and the right ventricular chamber via appropriately selected inter-ventricular pacing intervals (see Chinchoy column 5, lines 1-2, column 6, lines 58-61 and column 8, lines 7-20).

Chinchoy further discloses that any of the leads of the system (depicted in Figs. 1A-1B) in communication with the patient's heart could additionally include high-voltage cardioversion or defibrillation shock electrodes for delivering cardioversion/defibrillation therapy (see Chinchoy column 8, lines 21-28). It is inherent that such electrodes comprise coil electrodes. Chinchoy discloses the claimed invention as discussed above except that the sensor 62 is an accelerometer, not a tensiometric sensor.

Ferek-Petric, however, discloses a method for administering cardiac electrotherapy and an implantable electrotherapy apparatus employing a tensiometric-type transducer, read a sensor, to measure contractions of the heart muscle and subsequently control the administration of electrotherapy to the cardiac tissue (see Ferek-Petric Abstract). Ferek-Petric also discloses that the practical application of an accelerometer has the problems of oversensing of the human body acceleration which impedes accuracy, specifity and sensitivity of the sensor and that the radial acceleration of the lead at the point of accelerometer fixation is influenced by the intracardiac blood stream in such a way as to attenuate direct energy transfer from cardiac muscle to the accelerometer (see Ferek-Petric column 4, lines 14-26) and that a system employing a tensiometric-type sensor eliminates the oversensing and blood-stream influence on the signal improving accuracy, specifity and sensitivity of the sensor and employs a direct transfer of cardiac contraction energy to the mechanical stretching energy within the sensor (see Ferek-Petric column 4, lines 34-49).

Ferek-Petric further discloses that there is the possibility to use a standard pacing lead for tensiometric measurement and that the stylet channel of a lead enables the control of the lead implantation by means of a stylet insertion. After the proper positioning of the lead tip, the stylet

is pulled out therefore providing an empty stylet channel, which may be used for the permanent insertion of a tensiometric stylet (see Ferek-Petric Figs. 5-8 and column 5, lines 11-21). The Examiner also notes that Chinchoy discloses that sensor 62 may be embodied by any sensor capable of generating a signal proportional to left-ventricular lateral wall acceleration and makes reference to the Ferek-Petric invention (see Chinchoy column 2, lines 57-62 and column 3, lines 47-51). In addition the Examiner considers Chinchoy to be synonymous with Ferek-Petric since both sense cardiac contractions to optimize pacing therapy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor of Chinchoy in view of Ferek-Petric to include a tensiometric-type sensor comprising a stylet transvenous delivery mechanism coupled to the tensiometric-type sensor to improve the accuracy, specifity and sensitivity of the system and provide for control of the lead implantation by means of a stylet insertion.

5. As to Claim 2, Chinchoy discloses that the single mechanical sensor 62, located on endocardial left ventricular coronary sinus lead 52, is adapted to be coupled to a portion of a coronary sinus ostium, a portion of a coronary sinus and a portion of a cardiac vein (see Chinchoy Fig. 1A, column 5, lines 66-67 and column 6, lines 1-8 and lines 27-41).

6. As to Claim 3, Chinchoy discloses an additional mechanical sensor 60, located on right ventricular lead 32, adapted to mechanically couple to a discrete portion of the right ventricular chamber such as the right ventricular apical region and for detecting motion or acceleration of the right ventricular apical region (see Chinchoy Fig. 1A and column 5, lines 59-63). Chinchoy also discloses that physiological input signal processing circuit 108 of the processor-based

electronic pacing engine 14 receives signals from sensor 62 and sensor 60 (see Chinchoy column 7, lines 60-67).

7. As to Claim 8, Chinchoy discloses the claimed invention as discussed above except that it is not specified that the additional sensor 60 comprises an accelerometer sensor. The Examiner takes the position that it is inherent, or at least obvious to one having ordinary skill in the art, that the additional mechanical sensor 60, located on right ventricular lead 32, may comprise a single axis accelerometer or a multiple axis accelerometer since mechanical sensor 62 is capable of these embodiments and there appears to be no structural or operative difference between sensor 60 and sensor 62 (see Chinchoy Fig. 1A, column 5, lines 50-67 and column 6, lines 1-41).

8. As to Claim 10, Chinchoy discloses that sensor 60 is disposed on a intracardiac transvenous lead 32, read as a transvenous delivery mechanism.

9. As to Claim 11, Chinchoy discloses the claimed invention as discussed above except it is not specified that the transvenous delivery mechanism comprises one of a stylet, a single lumen delivery catheter and a guidewire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Chinchoy, with a transvenous delivery mechanisms comprising a stylet, guidewires or single lumen delivery catheter since it was known in the art that that such delivery mechanisms are used to appropriately place drugs, electrodes, sensors, transducers or the like transvenously.

10. As to Claims 12 and 17, Chinchoy discloses that processor-based electronic cardiac pacing engine 14 may be located in an implantable or external multi-chamber pulse generator (see Chinchoy Abstract and column 3, lines 35-46).

11. As to Claim 13, Chinchoy discloses that processor-based electronic cardiac pacing engine 14 may be located in an implantable cardioverter-defibrillator (see Chinchoy column 1, lines 8-12 and column 8, lines 35-40).

12. As to Claim 14, Chinchoy discloses that processor-based electronic cardiac pacing engine 14 further comprises a programmable medium 102 for executing computer readable instructions (see Chinchoy Fig. 2 and column 7, lines 29-47).

13. As to Claims 15 and 16, Chinchoy discloses that the computer readable medium 102 includes instructions for delivering a cardiac resynchronization therapy and delivery of pacing pulses to two or more heart chambers t by the selection of programmable pacing intervals, which can include atrial-atrial (A--A), atrial-ventricular (A-V), and ventricular-ventricular (V--V) intervals (see Chinchoy Title, Abstract and column 7, lines 29-59).

Response to Arguments

14. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sowelam et al. (U.S. 2005/0203579) teaches that it is known to use mechanical sensors such as accelerometers, tensiometric sensors, force transducers and the like to sense cardiac contractions.

Yu et al. (U.S. 2003/0105496) discloses methods and devices for employing mechanical measurements to synchronize cardiac contractions of ventricular wall locations.

Yu et al. (U.S. 6,923,772) teaches that accelerometers may be positioned in the lumen of a lead within the coronary sinus vein, minimizing the invasiveness of the accelerometer implantation.

Yu et al. (U.S. 6,980,866) discloses systems and methods for detecting and measuring cardiac contractile function of a heart using a single acceleration sensor inserted within the heart, such as within a vein of the cardiac wall alongside the left ventricular chamber or left atrial chamber.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 03/22/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
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